K072509

510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201 Fax: (215) 256-9191
Contact:	Jean Callow Regulatory Specialist
Date Prepared: NOV 2 6 2007	September 7, 2007

B. Trade Name:	Medcomp® PRO-PICC ™ CT
Common Name:	Peripherally Inserted Central Catheter
Classification:	LJS
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
C.F.R. Section:	880.5970 Class II

C. Predicate Device:	C.R. Bard, Inc. K053501 6Fr. TL PowerPICC™ Catheter Medcomp K053345 Pro-Line™ CT Pressure Injectable CVC.

D. Device Description:

The PRO-PICC ™ CT catheter is a triple lumen open-ended picc designed for power injection through one designated lumen. The catheter is an extension of the Medcomp® Pro-Line™ CT Power Injectable CVC (K053345) and Power Injectable Implantable Port (K070003) catheter line. The PRO-PICC ™ CT catheter is comprised of a soft radiopaque polyurethane material. The lumen has a reverse taper design and is connected to the extensions via a soft pliable hub with suture wing for secure placement. Clamps are provided on the extension tubes to prevent air/fluid communication. Female luer connectors provide the connection for intravenous administration. The designated power injectable extension line and clamp material are purple in color to differentiate it from the non-power injectable extensions and the purple lumen identifies it as a power injectable catheter. The center extension also is printed with the words power injectable. The I.D. Ring within the clamp on the power extension contains information regarding checking for blood return and flushing along with rate of infusion for power injection.

The PRO-PICC ™ CT catheter is available in 6F triple lumen. The catheter has a usable length of 60 cm with depth markings in 5 cm increments. Stylet and adaptor sideport are provided to assist in catheter insertion.

The catheter is packaged sterile in two radiology versions and two nursing configurations with the necessary accessories to facilitate catheter insertion.

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E. Intended Use:

The PRO-PICC ™ CT catheter is indicated for short term peripheral access to the central venous system for intravenous therapy and power injection of contrast media. For blood sampling, infusion, or therapies, use a 4F or larger catheter. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

F. Performance Data:

In vitro testing was performed on the PRO-PICC ™ CT catheter to assure reliable design and performance in accordance with ISO 10555-1 and 10555-3 and internal engineering protocol. Testing includes air/liquid leakage, force at break, elongation, gravity flow, static burst pressure, high pressure injection flow rate and chemical testing.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate devices.

All materials used for the proposed device were previously cleared in the Medcomp K053345 Pro-Line™ CT Pressure Injectable CVC. Biocompatibility testing on the Pro-Line™ CT Pressure Injectable CVC demonstrated that the materials used meets the requirements of ISO 10993 for a permanent external communicating blood contact device.

G. Comparison to Predicate Device:

The PRO-PICC ™ CT catheter is substantially equivalent to the predicate devices in terms of intended use, insertion method, anatomical location, design, materials, performance, labeling, packaging and method of sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 6 2007

Ms. Jean Callow
Regulatory Specialist
MedComp
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K072509
Trade/Device Name: PRO-PICC ™ CT
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: September 6, 2007
Received: September 17, 2007

Dear Ms. Callow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): _____

Device Name: ___ PRO-PICC ™ CT _____

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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